



10 November 2016
EMA/CHMP/SAWP/743808/2016
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 7 – 10 November 2016

Pre-authorisation: scientific advice and protocol assistance EMA centralised procedures

	1995 - 2015	2016	Overall total
Scientific Advice	2899	292	3191
Follow-up to Scientific Advice	846	78	924
Protocol Assistance	662	66	728
Follow-up to Protocol Assistance	310	38	348
HTA parallel advice	63	19	82
Qualification of novel methodologies	83	10	93
	4863	503	5366

Outcome of the November 2016 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications(s)	Type of request				Topic			Significant Benefit
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	
		SA	PA	SA	PA				
Chemical	Treatment of chronic heart failure.	x						x	
Other innovative	Treatment of gut dysbiosis-related complications.	x				x	x	x	
Chemical	Treatment of biliary atresia post-hepatopertoenterostomy.	x						x	
Biological	Treatment of congenital hyperinsulinism.		x				x	x	



Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x		x			
Chemical	Treatment of non-metastatic castration-resistant prostate cancer.			x		x			
Chemical	Treatment of cholangiocarcinoma.		x				x	x	
Chemical	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of ovarian cancer.	x						x	
Biological	Treatment of triple negative breast cancer.	x						x	
Chemical	Treatment of microscopic polyangiitis.				x	x		x	
Chemical	Treatment of granulomatosis with polyangiitis.				x	x		x	
Chemical	Treatment of chronic myeloid leukaemia and acute lymphoblastic leukaemia.			x				x	
Biological	Treatment of primary haemophagocytic lymphohistiocytosis.		x			x			
Biological	Treatment of ulcerative colitis, Crohn's disease, rheumatoid arthritis.	x					x		
Chemical	Treatment of chronic Graft vs Host disease.	x						x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x		x	x		
Biological	Treatment of non-small cell lung cancer.	x					x	x	
Chemical	Treatment of acute myeloid leukaemia.	x					x	x	
Biological	Treatment of non-small cell lung cancer.	x				x		x	
Chemical	Treatment of breast cancer.			x				x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of basal cell carcinoma.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of castration resistant prostate cancer.	x						x	
Chemical	Treatment of pyruvate kinase deficiency.	x					x	x	
Biological/ Advanced therapy	Treatment of immunodeficiency.		x					x	x
Biological	Treatment of refractory antibody-mediated rejection.	x					x	x	
Chemical	Treatment of haemophilia A/B.				x			x	
Biological	Treatment and prophylaxis of bleeding in congenital hypo-, dys- or afibrinogenaemia.	x				x	x	x	
Biological	Treatment of acquired hypofibrinogenaemia.	x				x	x	x	
Chemical	Treatment of multiple myeloma.		x					x	
Advanced therapy	Treatment of beta thalassemia.		x			x		x	
Biological	Treatment of Netherton syndrome.		x			x		x	
Chemical	Treatment of atopic dermatitis.	x						x	
Chemical	Treatment of epidermolysis bullosa acquisita.	x						x	
Advanced therapy	Treatment of ADV infection.		x				x	x	
Chemical	Treatment and prevention of Clostridium difficile infection.	x					x	x	
Chemical	Treatment of influenza A or B infection.			x			x	x	
Biological	Treatment of osteoporosis and giant cell tumour of the bone.	x					x	x	
Biological	Treatment of osteoarthritis pain and chronic low back pain.	x					x	x	
Biological	Treatment of prodromal Alzheimer's disease.	x					x	x	
Chemical	Treatment of Alzheimer's disease.	x					x	x	
Chemical/ Other innovative	Treatment of major depressive disorder.			x				x	
Chemical	Treatment of chronic somatic pain and peripheral neuropathic pain.	x					x	x	
Chemical	Treatment of TTR familial amyloid polyneuropathy.		x					x	

Substance	Intended indications(s)	Type of request				Topic			Significant Benefit
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	
		SA	PA	SA	PA				
Chemical	Treatment of Alzheimer's disease.	x				x			
Chemical	Treatment of asthma.	x						x	
Chemical	Treatment of chronic obstructive pulmonary disease.	x					x	x	
Biological	Treatment of asthma.			x				x	
Chemical	Treatment of dry eye disease.	x					x	x	
Chemical	Treatment of mucopolysaccharidosis.	x					x	x	
Chemical	Treatment of chronic kidney disease on dialysis.			x				x	
Chemical	Treatment of chronic kidney disease on dialysis.	x				x	x		

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 32 Scientific Advice letters, 9 Protocol Assistance letters, 9 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 HTA Parallel advice, were adopted at the 7 – 10 November 2016 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 48 new Requests for which the procedure started at the SAWP meeting held on 24 - 27 October 2016. The new requests are divided as follows: 20 Initial Scientific Advice, 13 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 7 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 HTA Parallel advices.